Atrium Medical Announces 1-year results of the INFUSE-AMI Trial

PR Newswire

HUDSON, N.H., May 3, 2013 /PRNewswire/ -- Atrium Medical Corporation, a business unit of MAQUET Cardiovascular, today announced the 1-year results of the INFUSE-AMI (Abciximab and Aspiration Thrombectomy in Patients With Large Anterior Myocardial Infarction) trial. Dr. Gregg Stone , the principle investigator, presented the exciting findings at the 62nd Annual American College of Cardiology Conference in San Francisco, CA.

INFUSE-AMI's primary endpoint was reduction in infarct size (also known as the size of the heart muscle impacted by a heart attack) measured by the highly sensitive cMRI, at 30-days in patients who were treated with intra-lesional ClearWay™ RX /abciximab* versus those that did not receive intra-lesional ClearWay RX/ abciximab.

At 30-days, the primary endpoint was achieved, and patients who were treated with intra-lesional ClearWay RX/abciximab experienced a statistically significant relative reduction in infarct size of 16%. Additionally, patients in the ClearWay RX /abciximab arm showed a favorable trend in new onset of severe heart failure in comparison to those patients that did not receive this treatment.

Clinical findings between 30-days and 1-year for patients who received intra-lesional ClearWay RX/abciximab were strongly associated with better outcomes, including significantly lower mortality rates and reduced major adverse cardiac and cerebral events compared to patients who did not receive ClearWay RX/abciximab.

Researchers also observed all mortality occurred in patients with an infarct size greater than 17.1%** (the median infarct size in the INFUSE-AMI trial was 17.2%). The median infarct size for patients treated with ClearWay RX/abciximab was 15.1%, whereas the median infarct size for patients who received an alternative treatment was 17.9%. The INFUSE-AMI data shows a relationship between infarct size and mortality. These clinical findings correlate with other published studies and could explain some of the improved results in those patients receiving intra-lesional abciximab via the ClearWay RX drug delivery balloon.

Dr. Michael Gibson , Co-PI for the INFUSE-AMI trial, stated that "ClearWay offers the interventionalists a reproducible, on the table treatment option for the preservation of heart muscle, resulting in reduced clinical events, and was associated with a mortality reduction in this mechanistic study."

About the ATRIUM MAQUET ClearWay™ RX Drug Delivery Balloon Catheter
The ClearWay RX local drug delivery balloon catheter is a thin, microporous PTFE balloon mounted on a .014" rapid exchange catheter, FDA 510(k) & CE cleared for

the delivery of therapeutic and diagnostic agents in the coronary and peripheral vasculature. The ClearWay RX balloon atraumatically occludes blood flow during the local infusion, thus maximizing the therapeutic agent's concentration and residence time enhancing the desired therapeutic effect. ClearWay RX is available in 1.0 to 4.0 mm balloon diameters and in balloon lengths ranging from 10 to 50 mm. As of October 1, 2012 the ClearWay RX drug delivery balloon was added to the ACC guidelines as an approved device meeting the criteria for "door to balloon" time (SEQ7050-51).

About Atrium Medical Corporation
Atrium Medical Corporation's vast expertise in medical device technologies for the treatment of coronary and vascular disease, chest trauma, hernia and soft tissue injury has brought a number of breakthrough advances in several diversified healthcare markets including interventional cardiology and radiology, chest trauma care and thoracic drainage, vascular surgery, and general surgery. Maintaining a commitment to the latest ISO13485 Quality Standards, state-of-the-art manufacturing and automation, cell biology and biomaterial discovery programs, Atrium continues to excel in those healthcare segments that require more advanced surgical intervention for improvements in patient outcomes. Atrium is a business unit of MAQUET Cardiovascular, a member of the GETINGE GROUP of companies. For more information please visit www.atriummed.com [1].

About MAQUET
MAQUET, a trusted partner for hospitals and physicians for over 175 years, is the global leader in providing medical systems that meet the needs of the most medically challenging patients, while exceeding the expectations of the hospital teams that care for them. MAQUET designs, develops and distributes innovative therapy solutions and infrastructure capabilities for high-acuity areas within the hospital including the operating room (OR), hybrid OR/cath lab and intensive care unit (ICU) as well as intra and inter hospital patient transport.

Headquartered in Rastatt, Germany, MAQUET is the largest subsidiary of the publicly listed Getinge Group AB of Sweden. MAQUET generated about 1.5 billion Euros in 2012, representing more than half of the Getinge Group's annual revenue of 2.7 billion Euros. MAQUET has 6,300 employees in 45 international sales and service organizations, as well as a network of more than 300 sales representatives. For more information please visit www.maquet.com [2].

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